

EXHIBIT 2

The Impact of Growth in 340B Contract Pharmacy Arrangements – Six Years Later

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AIR_x340B
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Introduction

In 2014, the Alliance for Integrity and Reform of 340B (AIR340B) published a paper highlighting the negative impact the growth in contract pharmacy arrangements was having on the 340B program.¹ AIR340B concluded the paper with a thoughtful, non-exhaustive list of suggested improvements to the 340B program. Six years later, these suggestions, ranging from ideas to ensure that patients benefit from the discounts to measures to improve program integrity, have yet to be considered by policymakers. However, over that same time, attention to how contract pharmacies are operating has proven to be even more important as the 340B program continues to grow without sufficient guardrails in place to make sure it remains true to its original objective.² Additionally, since AIR340B's paper was published, the Government Accountability Office (GAO) has written multiple reports documenting some of the same issues AIR340B flagged, and multiple 340B stakeholders, researchers, and thought leaders have documented how the growth in contract pharmacies is contributing to the program's ballooning size without any accompanying guarantee of patient benefit.

Based on a review of existing government reports, expert studies, and media articles, this paper seeks to highlight the statistics, analytics and examples of the negative impact that continued growth in the contract pharmacy program is having and how, after six years, the chorus of voices calling for reform to this program has only grown while the benefit to the patient remains elusive.

Growth of 340B Contract Pharmacies

The 340B program currently represents 11 percent, or \$67.4B, of total US drug sales and has grown five times faster than the growth rate of the overall drug market.³ The size and scope of 340B today resembles nothing like the program created by Congress in 1992. One component driving the tremendous growth of the 340B program is contract pharmacies. Not included in the 340B statute and created by Health Resources and Services Administration (HRSA) guidance in 1996 with further expansion in 2010, contract pharmacies have helped shape today's bloated 340B program with no guarantee that patients see a benefit from the involvement of these for-profit retail pharmacy chains.

Growth in the number of contract pharmacies and contract pharmacy arrangements was on the rise when AIR340B wrote its 2014 paper, however no one could have forecasted the accelerated growth that has occurred in the six years since that paper was published. Since HRSA expanded the 2010 guidance to allow a covered entity to contract with an unlimited number of contract pharmacies, the number of for-profit pharmacies participating in 340B has skyrocketed from 1,300 to close to 28,000.⁴ According to a Berkeley Research Group analysis, following HRSA's expansion of the contract pharmacy program in March 2010, contract pharmacy participation grew 4,228 percent between April 2010 and April 2020.⁵ Those contract pharmacies are involved in more than 112,000 arrangements with more than 8,000 covered entities; approximately 75 percent of

1 <http://340breform.org/userfiles/FINAL.The%20Impact%20of%20Growth%20in%20340B%20Contract%20Pharmacy%20Arrangements.%20AIR%20340B.%20July%202014,%202014.pdf>

2 "[340B] has expanded beyond its bounds." Kathleen Sebelius, Former HHS Secretary, US Senate Committee on Finance hearing on President's FY 2015 health care proposals, April 10 2014

3 <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/340b-complexities-challenges-and-change-whitepaper.pdf>

4 <https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html>

5 https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

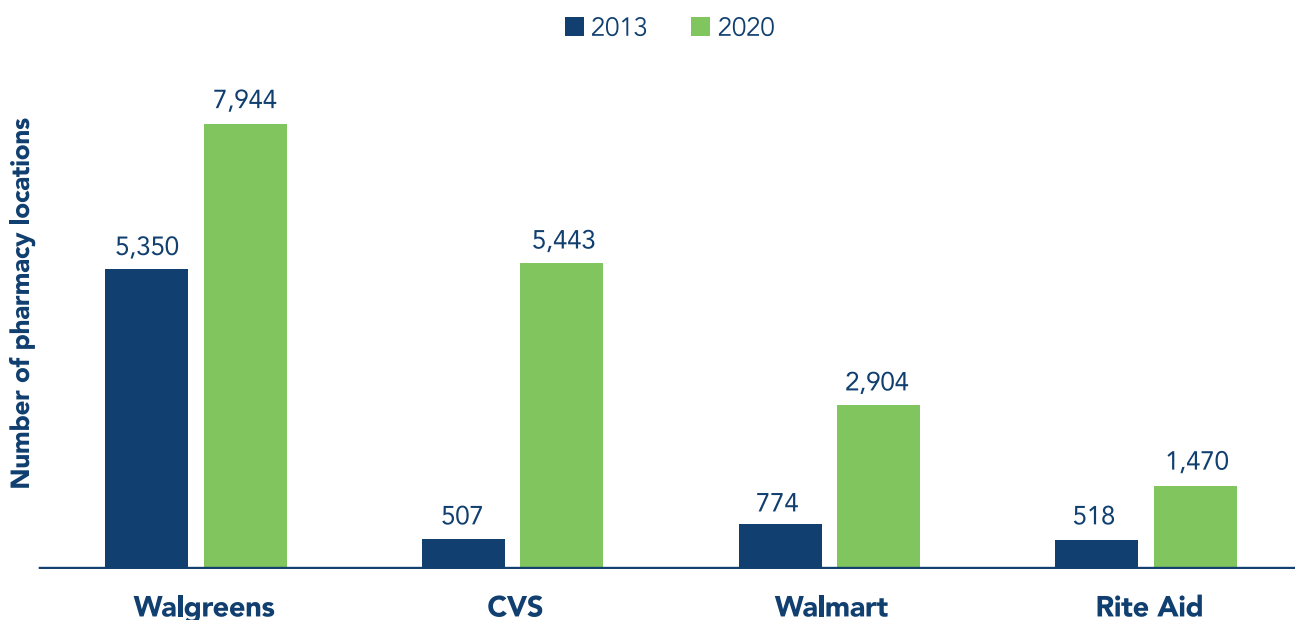
those covered entities are either disproportionate share (DSH) or children's hospitals.⁶

The majority of contract pharmacy arrangements continue to be large for-profit retail chains (75 percent) like CVS and Walgreens, a troublesome fact as contract pharmacies are not listed in the 340B statute and the 340B program was created to support non-profit providers serving vulnerable or uninsured communities. Drug Channels' analysis of the state of the contract pharmacy landscape shows that since AIR340B's first paper on contract pharmacies was released, for-profit retail chain pharmacies continue to play a larger and larger role in the program. The economics of why it is appealing to them will be

addressed later in this paper.

Contract pharmacy growth on its own isn't inherently a problem. In fact, if exponential growth of 340B contract pharmacy arrangements meant they were helping to serve covered entities without their own in-house pharmacies and ensuring 340B discounts were being used for low income and vulnerable 340B patients, growth in contract pharmacies would be a positive thing. But growth of that magnitude raises questions for policymakers to consider especially when there is growing evidence that program integrity problems persist and patients are not always benefiting.

340B Contract Pharmacy Locations, by Chain, 2013 vs. 2020



Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique pharmacy locations as of July 1, 2020. Company totals are computed from combined banners (store names) in the database.

Published on Drug Channels (www.DrugChannels.net) on July 14, 2020.

⁶ <https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html>

For Further Reading:

- ✓ Berkeley Research Group – “Measuring the Relative Size of the 340B Program: 2018 Update”⁷
- ✓ 340B Commission’s Final Report on the 340B Drug Discount Program - “The Issues Spurring Discussion, Stakeholder Stances and Possible Resolution”⁸
- ✓ Wall Street Journal Op-Ed – “The Federal Program that Keeps Insulin Prices High”⁹

Why Patients See Little Benefit from Contract Pharmacies

Since 2014, the Office of Inspector General (OIG) and GAO have published 340B oversight reviews on contract pharmacies. Their reports have focused on some of the program integrity issues, which AIR340B highlighted in its 2014 paper. However, their analyses have gone beyond program integrity and have also raised one of the core concerns many policymakers have about how 340B operates: Is it operating in a way that patients see a benefit from the steep discounts that drug manufacturers provide?

AIR340B’s 2014 paper highlighted the OIG report findings. The OIG report provided evidence that the contract pharmacy program may often

fail to provide assistance to vulnerable patients facing barriers in filling their prescriptions. Of the 15 DSH hospitals the OIG interviewed for its 2014 report, only one-third reported that they offer the 340B-discounted price to uninsured patients in at least one of their contract pharmacy arrangements.¹⁰ As OIG stated in their report, if covered entities do not offer the 340B price to uninsured patients, “their uninsured patients pay the full non-340B price for prescriptions filled at contract pharmacies.”¹¹

The results of the OIG’s analysis were concerning, however what is more concerning is that four years later, the GAO did a more detailed analysis that found very little had changed in how contract pharmacies interact with patients. Nearly half of the covered entities interviewed by the GAO did not provide discounted drug prices to low-income, uninsured patients who filled prescriptions at the covered entity’s 340B contract pharmacy.¹² That percentage is worse when survey respondents were limited to hospitals. 57 percent of hospitals reported to the GAO that they did not provide discounted drug prices to low-income, uninsured patients filling prescriptions at the covered entity’s contract pharmacy.¹³ Contributing to this problem is the lack of consistency with which covered entities identify patients. Both OIG and GAO found that covered entities apply varied methods to identify 340B-eligible prescriptions. Oftentimes, a prescription is not determined to be 340B-eligible until after it has been filled and the patient may have been charged the full price.^{14 15}

The expansive growth of DSH hospitals and contract pharmacies has increased profits for DSH hospitals, but this has not necessarily

7 <https://www.thinkbrg.com/insights/publications/measuring-the-relative-size-of-the-340b-program-2018-update/>

8 http://www.tiicann.org/pdf-docs/2019_CANN_340B_Commission_Final-Report-v5_03-07-19.pdf

9 <https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-high-11599779400>

10 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>

11 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>

12 <https://www.gao.gov/assets/700/692697.pdf>

13 <https://www.gao.gov/assets/700/692697.pdf>

14 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>

15 <https://www.gao.gov/assets/700/692697.pdf>

translated into better health outcomes for low-income Americans.¹⁶ A review of the unintended consequences of the 340B program written in *Health Services Research* summed up the impact that the 340B program, including the growth of contract pharmacies, has had on safety-net providers treating vulnerable patients. The authors wrote “the literature now suggests that the 340B program has offered a major financial windfall to covered entities with little of the benefit targeted toward safety-net providers who care for low-income patients.”¹⁷

An analysis performed by the Center for Regulatory Effectiveness (CRE) compared the relative affordability of needed prescription drugs, medical care, and dental care for the most medically underserved communities with the growth in the number of contract pharmacies. The authors of the CRE report wrote that in regard to the growth of contract pharmacies, “it is evident that the ability of people suffering severe economic hardship to afford needed medicines and medical care, relative to the general population, is negatively correlated with growth in the 340B program.”¹⁸

What is significant to point out is more what is not here than what is. The common theme among these analyses is that there is next to no data evaluating or demonstrating whether expanding the scope of 340B prescription distribution to for-profit chain pharmacies has made a beneficial impact on patients. This compilation of sources shows that while there are numbers documenting the program’s growth (both in the number of participating entities and in the dollars flowing

through the program), beyond documenting the number of contract pharmacies participating in the program, there is still no guarantee patients are benefiting from contract pharmacies and, if they are, to what extent.

For Further Reading:

- ✓ OIG – “Contract Pharmacy Arrangements in the 340B Program”¹⁹
- ✓ GAO – “Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement”²⁰
- ✓ Marshall University – “The 340B Program, Contract Pharmacies and Hospitals: An Examination of the First 25 Years of their Increasingly Complex Relationship”²¹
- ✓ Health Services Research – “The Unintended Consequences of the 340B Safety-Net Drug Discount Program”²²
- ✓ Center for Regulatory Effectiveness – “Measuring the Effectiveness of the 340B Program”²³
- ✓ Miami Herald Op-Ed – “On World AIDS Day, Let’s Remember Disease is Still a Brutal Killer”²⁴
- ✓ New England Journal of Medicine – “Consequences of the 340B Drug Pricing Program”²⁵

16 https://mds.marshall.edu/cgi/viewcontent.cgi?article=1204&context=mgmt_faculty

17 <https://onlinelibrary.wiley.com/doi/abs/10.1111/1475-6773.13281>

18 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078

19 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>

20 <https://www.gao.gov/assets/700/692697.pdf>

21 https://mds.marshall.edu/cgi/viewcontent.cgi?article=1204&context=mgmt_faculty

22 <https://onlinelibrary.wiley.com/doi/abs/10.1111/1475-6773.13281>

23 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078

24 <https://www.miamiherald.com/opinion/op-ed/article187445323.html>

25 <https://www.nejm.org/doi/full/10.1056/NEJMsa1706475>

The Economics of Contract Pharmacies

While the impact that contract pharmacy growth has had on patients is unknown, what is known is why increased participation in the 340B program is financially beneficial for for-profit retail pharmacies.

Fees and Impact on Generic Dispensing

340B contract pharmacies typically earn per-prescription fees paid by the 340B entity.²⁶ These arrangements were outlined by the GAO²⁷ and, as analyzed by Drug Channels, essentially fall into three categories:²⁸

- 1 Flat fee. In some cases, the flat fees differed and were higher for brand prescriptions vs. generic prescriptions
- 2 Flat fee + percent of negotiated reimbursement between payer and pharmacy
- 3 Flat fee + percent of difference between negotiated reimbursement between the pharmacy and payer and the 340B acquisition cost

Under these fee structures, pharmacies have the potential to make more money on brand prescriptions either because flat fees are higher for branded prescriptions or as a function of the larger gap between the reimbursement

amount and the acquisition cost for brand drugs compared to generic drugs.²⁹ Based on these economics, a percentage based fee is expected to increase when there is a larger gap between the reimbursement amount and discounted acquisition cost. The GAO found that DSH hospitals were commonly establishing contracts with chain pharmacies where the contract pharmacy was paid 15-20 percent of the total reimbursement (including patient cost sharing) for the 340B prescription.³⁰ The economics of the 340B program, and contract pharmacies specifically, suggest that contract pharmacies are for-profit middlemen who making profits off higher-cost drugs, which can lead to higher costs for patients. When the total cost of a prescription prescribed to a patient increases, the patient's benefit design (deductible and/or coinsurance) can lead to higher out-of-pocket costs if a hospital or contract pharmacy charges a patient a price more than the 340B acquisition price.^{31 32} The GAO's analysis showed that in some instances, covered entities paid more for branded drugs, and in other cases, limited the use of the 340B program to branded prescriptions only by excluding generics from being purchased at the 340B price. This may help explain why the 340B program discourages use of generic drugs and why 90 percent of 340B utilization is on branded drugs, versus 77 percent in the US market overall.³³ This is also supported by research published in *Health Affairs*, which found "contract pharmacies for 340B hospitals disproportionately favor branded, patent-protected drugs over generic therapeutic substitutes, overall, and within a therapeutic

26 http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch15_sec.pdf?sfvrsn=0

27 <https://www.gao.gov/assets/700/692697.pdf>

28 <https://www.drugchannels.net/2018/12/gao-confirms-it-340b-hospitals-and.html>

29 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4545491/>

30 <https://www.gao.gov/assets/700/692697.pdf>

31 <https://www.politico.com/newsletters/prescription-pulse/2018/07/02/perverse-incentives-why-some-340b-pharmacies-are-opting-for-branded-drugs-268802>

32 <https://www.gao.gov/assets/700/692697.pdf>

33 <https://www.thinkbrg.com/insights/publications/measuring-the-relative-size-of-the-340b-program-2017-update/>

class—a pattern that does not appear to be driven by a patient’s clinical complexity alone.”^{34 35}

The entry of for-profit retail pharmacies into a program meant for non-profit entities has created a system of financial incentives where contract pharmacies seem to be driving up the usage of more expensive medications because of the ability to generate percentage-based fees (ranging from 12-20 percent per script). These pay structures could be in large part why it is appealing for for-profit retail pharmacies to become a 340B contract pharmacy. As explained earlier in this paper, today, while more than 28,000 distinct pharmacies³⁶ participate in the 340B program, BRG estimates that more than half of the 340B profits retained by contract pharmacies are concentrated in just three pharmacy chains (Walgreens, Walmart, CVS Health) and Cigna’s Accredo specialty pharmacy.³⁷ Health economist Rena Conti explains the issue most clearly when asked about the GAO’s 2018 analysis of contract pharmacies: “Here’s a policy that is maximizing revenue for hospitals and contract pharmacies and perversely going against the intent of the program, which is to provide accessible and affordable health care for vulnerable people.”³⁸

These OIG and GAO analyses suggest more information is needed to understand how fees and the profits these for-profit, retail contract pharmacies are generating are being earned on prescriptions for which some low-income, uninsured patients paid full price.

Vertical Integration

Since contract pharmacies were created through sub-regulatory guidance in 1996, a cottage industry of for-profit companies has emerged, marketing their services as the best way for contract pharmacies to maximize their 340B profitability.³⁹ BRG estimated that the average profit margin on 340B prescriptions commonly dispensed through contract pharmacies is 72 percent, compared with just 22 percent for non-340B prescriptions dispensed through independent pharmacies.⁴⁰ Additionally, the emergence of vertical integration in the contract pharmacy space suggests that 340B profits are just too big for these large companies to ignore.

The distorted economics of contract pharmacies doesn’t stop with for-profit, chain pharmacies. As the health care landscape has evolved and the 340B program is reaching record sales, experts see contract pharmacy economics as now extending and exacerbating the growing trend of vertical integration within the health system.⁴¹ Vertical integration of pharmacies, PBMs, and payers is an emerging trend, driving up the cost of health care for patients. Over half of the 340B profits retained by contract pharmacies are concentrated in just four pharmacy corporations. These entities are also likely to be associated with a health plan, pharmacy benefit manager, specialty pharmacy, or third-party administrator through common ownership or other affiliation. These integrated, for-profit PBMs are keeping more of the manufacturer provided discounts, raising questions about the operations of a program meant to benefit needy patients.^{42 43}

34 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4545491/>

35 <https://www.ajmc.com/view/three-proposals-to-reform-the-340b-drug-discount-program>

36 <https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html>

37 https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

38 <https://www.politico.com/newsletters/prescription-pulse/2018/07/02/perverse-incentives-why-some-340b-pharmacies-are-opting-for-branded-drugs-268802>

39 http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf

40 https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

41 <https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>

42 <http://thecapitolist.com/protect-floridians-access-to-affordable-prescription-drugs/>

43 <https://www.dispatch.com/news/20200113/pharmacy-middlemen-benefit-from-drug-discount-program-intended-to-help-poor-ohioans>

340B third-party administrators (TPAs) are one example of the for-profit, third-party players in the program. They contract with hospitals to provide billing software and compliance tools to administer the covered entities' 340B program. In some instances, contract pharmacies and TPAs are also under common ownership, potentially raising concerns about conflicts of interest, if 340B prescriptions are routed and billed through the same entities. CVS Pharmacy was the subject of a federal district lawsuit in Florida alleging that the pharmacy chain violated antitrust laws after it expanded its business into 340B administration when it purchased 340B administrator Wellpartner. Following the acquisition, CVS allegedly announced that it would require all providers that use CVS as a contract pharmacy to use Wellpartner for 340B compliance services, or risk losing access to the CVS pharmacy network.⁴⁴

The dollars and profit opportunities at stake in the 340B program have played a role in restructuring the health care system so that "vertically integrated supply chains consisting of pharmacies, pharmaceutical benefit managers (PBMs) and health plans can leverage their market power to drive growth in the 340B program and capture profits related to 340B sales."⁴⁵ The concentrated power present in these for-profit, vertically integrated companies provides dominant bargaining power and leads to anticompetitive behavior stemming from the financial incentives inherent in contract pharmacies' participation in 340B, which can lead to higher health care costs for patients and for the system.

For Further Reading:

- ✓ IQVIA – "The 340B Drug Discount Program: Complexity, Challenges and Change"⁴⁶
- ✓ Berkeley Research Group – "For-Profit Pharmacy Participation in the 340B Program"⁴⁷
- ✓ The Columbus Dispatch – "Pharmacy Middlemen Benefit from Drug Discount Program Intended to Help Poor Ohioans"⁴⁸
- ✓ The Capitolist Op-Ed – "Protect Floridians' Access to Affordable Prescription Drugs"⁴⁹
- ✓ Health Affairs – "The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies In 2012"⁵⁰

Program Integrity

According to an analysis by BRG, when viewed in absolute dollars, 340B is the second largest prescription drug program by reimbursement, behind only Medicare Part D. That means that in 2018, reimbursement for 340B-purchased drugs exceeded Medicaid, Medicare Part B, and Tricare/DOD. Despite the fact that 340B discounted drugs provided by manufacturers play an outsize role in drug reimbursement

44 CVS settled with the plaintiffs in September 2019 - <https://www.sentryds.com/sentry-data-systems-reaches-settlement-agreement-with-cvs-and-wellpartner/>

45 https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

46 <https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program>

47 https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

48 <https://www.dispatch.com/news/20200113/pharmacy-middlemen-benefit-from-drug-discount-program-intended-to-help-poor-ohioans>

49 <http://thecapitolist.com/protect-floridians-access-to-affordable-prescription-drugs/>

50 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4545491/>

programs, many believe that HRSA, the agency which oversees and administers the 340B program, has insufficient resources to properly regulate the covered entities and contract pharmacies participating in the program.^{51 52}

Nowhere is this imbalance more evident than in the lack of oversight over contract pharmacies and the role their growth plays in exacerbating program integrity issues. AIR340B's 2014 paper laid out the detailed concerns around how the growth of contract pharmacies compounds the issue of diversion and duplicate discounts.⁵³

While the statute prohibits two practices covered entities must comply with – diversion, which prohibits a covered entity from reselling or transferring a 340B drug to an individual who is not a patient of the entity,⁵⁴ and duplicate discounting, the payment of a duplicate 340B and Medicaid discount on the same drug⁵⁵ – evidence suggests a significant lack of compliance with these requirements in the contract pharmacy context.⁵⁶ Manufacturers are oftentimes unable to identify from invoices which drugs have been subject to 340B discounts and/or other rebates.

HRSA's 2010 guidance made clear that it expected as part of multiple contract pharmacy arrangements, covered entities would need to adhere to certain program integrity practices to mitigate risks with contract pharmacies, stating

that, “covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts...”⁵⁷ However, today's contract pharmacy program falls short of meeting critical assumptions at the heart of ensuring program integrity.

The 2014 OIG report found that contract pharmacy arrangements make it more difficult for duplicate discounts and diversion to be identified by covered entities and HRSA.⁵⁸ The GAO followed up with its own analysis in 2018.⁵⁹ As an example, the GAO found that two-thirds of HRSA diversion audit findings involved medicines distributed through contract pharmacies. Additionally, the GAO found that HRSA does not have complete data on the total number of contract pharmacy arrangements in the 340B program to inform its oversight efforts and optimally target the number of risk-based audits. The GAO found that HRSA's program guidance lacks specificity and allows covered entities a great deal of discretion on the frequency and scope of their audits of contract pharmacies.⁶⁰

Both reports highlighted the lack of appropriate guidance and oversight from HHS over the program and linked the growth in both the size of the 340B program and the number of contract pharmacies as part of the cause of

51 https://media.thinkbrg.com/wp-content/uploads/2020/06/17122436/BRG-340B-Measuring_2020_cleaned.pdf

52 https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

53 <http://340breform.org/userfiles/FINAL.The%20Impact%20of%20Growth%20in%20340B%20Contract%20Pharmacy%20Arrangements.%20AIR%20340B.%20July%202014,%202014.pdf>

54 42 U.S.C. Sec. 256(b)

55 42 U.S.C. Sec. 256(a)(5)(A)(i)

56 Government Accountability Office, “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement” (Sept. 23, 2011); Office of Inspector General, “Memorandum Report: Contract Pharmacy Arrangements in the 340B Program,” OEI-05-13-00431, Feb. 4, 2014.

57 75 Fed. Reg. 10272, 10273 (March 5, 2010).

58 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>

59 <https://www.gao.gov/assets/700/692697.pdf>

60 HRSA began covered entity and manufacturer audits in 2012. Additionally, the 2010 contract pharmacy guidance recommends that covered entities perform annual independent audits of their contract pharmacies. However, this guidance has not resulted in meaningful action on the part of covered entities.

duplicate discounts. IQVIA reached these same conclusions stating, “contract pharmacies [are] the fastest growing 340B delivery model, [and] they’re also the most complex which increases the likelihood of duplicate discounts.”⁶¹ Yet again, over the last six years, not enough has been done to address these concerns.

For Further Reading

- ✓ Pharmacy & Therapeutics – “340B Program Puts Manufacturers at Risk of Duplicate Discounts”⁶²
- ✓ GAO – “Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement”⁶³
- ✓ CiiTA – “340B/Medicaid Duplicate Discount Risk to Manufacturers”⁶⁴
- ✓ OIG – “Contract Pharmacy Arrangements in the 340B Program”⁶⁵
- ✓ OIG – “State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates”⁶⁶
- ✓ GAO – “Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement”⁶⁷

Conclusion

The 340B program continues to grow, driven in large part by the growth of contract pharmacies. Contract pharmacies are a black box inside the already opaque 340B program and researchers and watchdog agencies are only beginning to scratch the surface of the profit-driven financial incentives at play. Under the 340B program, contract pharmacies are not required to share 340B profits with covered entities nor obligated to use discounts under the 340B program to help patients with the cost of their medication. In fact, the only data that exists on whether patients see a benefit from this growing program shows that in the majority of cases, they do not.^{68 69}

This updated review of the program shows that the issues highlighted by AIR340B in 2014 remain just as relevant today as they were then. New voices and analyses about problems with contract pharmacies have joined the conversation, however meaningful action to improve the program on behalf of patients and the health care system remains elusive.

While Congress has taken steps to provide some much needed oversight of the 340B program,^{70 71 72 73 74} AIR340B once again urges policymakers to take a closer look at this continuously growing program and put policies in place to increase its transparency and ensure that patients are benefiting from steeply discounted prescription drugs.

61 https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/340b-complexities-challenges-and-change-whitepaper.pdf?_=1602217006547

62 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699484/>

63 <https://www.gao.gov/assets/700/692697.pdf>

64 <http://ciitainc.com/wp-content/uploads/2015/08/Duplicate-Discounts-Risk-Whitepaper.pdf>

65 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>

66 <https://oig.hhs.gov/oei/reports/oei-05-14-00430.asp>

67 <https://www.gao.gov/products/GAO-20-212>

68 <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>

69 <https://www.gao.gov/assets/700/692697.pdf>

70 https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

71 <https://republicans-energycommerce.house.gov/news/press-release/ec-leaders-press-340b-contract-pharmacies-for-information/>

72 <https://www.help.senate.gov/hearings/effective-administration-of-the-340b-drug-pricing-program>

73 <https://www.help.senate.gov/chair/newsroom/press/alexander-federal-watchdogs-agree-that-340b-discount-drug-program-needs-better-oversight>

74 <https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/>

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